DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 9 2011

Re: NUEDEXTA
Patent Nos. RE38,115 and 5,206,248
Docket Nos. FDA-2011-E-0268
FDA-2011-E-0269

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. RE38,11 and 5,206,248 filed by Avanir Pharmaceuticals, Inc., under 35 U.S.C. § 156. The human drug product claimed by the patents is NUEDEXTA (dextromethorphan hydrobromide/quinidine sulfate), which was assigned new drug application (NDA) No. 21-879.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that NUEDEXTA does not represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1). The active ingredients in NUEDEXTA, dextromethorphan hydrobromide and quinidine sulfate, have been individually approved previously for commercial marketing or use in several other approved products including but not limited to the following:

Active Ingredient	Companies	Products	Application Numbers
Dextromethorphan Hydrobromide	Reckitt Benckiser	Mucinex DM (dextromethorphan hydrobromide and guaifenesin)	NDA 21-620
"	Multiple (Hi Tech Pharma, Vintage, Wockhardt, Actavis midAtlantic)	Dextromethorphan Hydrobromide in combination with either Pseudoephedrine Hydrochloride or Promethazine Hydrochloride	ANDAs[1] 40-027, 40-649, 88-811, 88-762, 88-864, 90-575

[1] ANDA = abbreviated new drug application.

Quinidine Sulfate	Wyeth Pharms, Inc.	Quinidex	NDA 12-796
"	Multiple (Teva Pharms, Mutual Pharm, Sandoz, Watson Laboratories	Quinidine Sulfate	ANDAs 40-045, 81-030, 81-031, 88-072, 83-288, 85-583

The NDA 21-879 was approved on October 29, 2010, which makes the submission of the patent term extension application on December 17, 2010, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Kevin G. Shaw
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